A Proposed Partnership to Achieve Data Quality Assurance through a National Laboratory Accreditation Program

by

National Environmental Laboratory Accreditation Conference (NELAC)
Board of Directors – Special Committee on National Accreditation

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PURPOSE

This report was prepared by a Special Committee appointed by the National Environmental Laboratory Accreditation Conference (NELAC) Board of Directors. The Special Committee represents a broad spectrum of federal, state and regulated community stakeholders with a common belief that accurate, reliable data are critical to making sound regulatory and environmental management decisions. Environmental data are generated by thousands of private sector and government laboratories and field-based organizations. Therefore, the task of assessing competence and ensuring and documenting data quality is complex and resource intensive.

To this end, the Environmental Protection Agency (EPA) has established a Quality System (QS) comprised of sampling and analytical methods, quality assurance policies and procedures to fulfill its mandate to ensure and document the quality of the data it relies on and disseminates (1-3). As an essential QS element, the EPA and states have established various laboratory certification and accreditation programs designed to assess and ensure competency of the laboratories that provide compliance data. However, these programs have differing requirements, applicability and effectiveness. While very significant progress has been made toward establishment of a national accreditation program by the creation of the National Environmental Laboratory Accreditation Program (NELAP), there still is not a consistent and comprehensive national program that effectively ensures laboratory competence and data quality for all drinking and waste water, solid waste and air programs that EPA and the states manage.

The Special Committee and Board of Directors suggest that the NELAP offers an optimal framework for EPA and the states to establish such a program. An integral part of achieving the objectives of a national program is the open participation by all federal, state, municipal, tribal and private sector stakeholders. However, without direct involvement, strong support and leadership from EPA program offices, we believe that the NELAP goal of establishing an effective and consistent national laboratory accreditation program will be very difficult to achieve.

The transition to self-sufficiency provides a fresh opportunity to explore how the NELAC Standard can be improved and NELAP program managed to better respond to EPA program office needs. ***We suggest that EPA and the states can most effectively and efficiently meet their data quality assurance mandates through existence of a national laboratory accreditation program and requiring that all environmental compliance monitoring data be generated by laboratories accredited by this program.***

HISTORY

The environmental testing community has for years been advocating a national accreditation program as the foundation for ensuring the capability and competence of laboratories and generation of data of known and documented quality. In addition to accreditation requirements for laboratories that analyze lead in paint and asbestos, EPA, with the states as its implementation partners, maintains requirements for the certification of drinking water laboratories. Many states have independently established accreditation programs covering the analysis of waste waters, solid and hazardous wastes, and air samples.

Almost twenty years ago, EPA recognized the problem of uncoordinated, inconsistent and redundant state and federal laboratory accreditation programs. In a 1988 Report to Congress on the comparability of laboratory test procedures, the EPA recommended that it explore the feasibility of establishing a uniform, national laboratory accreditation program (4). In response, EPA chartered the Committee on National Accreditation of Environmental Laboratories (CNAEL), which recommended that a national program for laboratory accreditation be established (5). This resulted in the formation of NELAC to establish a consistent, rigorous and practical set of accreditation standards and NELAP to implement those standards.

NELAC AND NELAP ACCOMPLISHMENTS

With generous financial and staffing support from the EPA Office of Research and Development (ORD), NELAC and NELAP were established. While voting on final adoption was limited to governmental representatives, the NELAC Standard for laboratory accreditation was developed through a committee system with participation by all affected stakeholders. Today, the thirteen NELAP state agencies accredit over 1,000 laboratories of all sizes for the analysis of drinking water, waste water, solid and hazardous waste, and air samples. Although this is only a fraction of the laboratories performing environmental testing, most commercial laboratories conducting interstate business are NELAP accredited.

The Departments of Defense (DOD) and Energy (DOE) as well as many waste generators, dischargers and permittees specify NELAP accreditation as an essential QS element to ensure the quality of their data. Many other successes are directly attributable to NELAP, including the requirement that laboratories implement the rigorous internationally recognized ISO/IEC quality system standard, better and more consistent assessor training and assessments, a reduction in the number and frequency of duplicative audits, and an increased emphasis on ethical practices and data integrity.

NELAP in partnership with EPA representatives has also successfully implemented an effective Proficiency Testing (PT) program which meets the needs of the EPA water supply, water pollution and the Discharge Monitoring Report – Quality Assurance (DMR-QA) programs. Through the NELAC Standards, the proficiency testing requirements have been re-evaluated and made more defensible, expanded to meet nearly all laboratory accreditation needs, and adopted uniformly by the states. These are testaments not only to the applicability and scope of the NELAC Standard but also to the commitment of the NELAC community to ensuring data quality.

AREAS FOR IMPROVEMENTS

The progress made by NELAP in just a few years should not be understated. However, with over 11,000 laboratories in the United States performing environmental analyses, there is a long way to go in reaching the goal of a rigorous nationally consistent laboratory accreditation and data quality assurance program. Until required, there is little incentive for those laboratories not NELAP-accredited to voluntarily comply with the NELAC Standard. Thirteen state agencies have voluntarily become NELAP accrediting authorities. Many more states, while choosing to not become

NELAP accrediting authorities, have selectively implemented parts of the NELAC Standard. The remaining state programs have not implemented the Standard for a variety of reasons, such as absence of a statutory or regulatory requirement and lack of resources and support to help them make the necessary program changes.

As a result, many state laboratory accreditation programs impose different and often unique requirements and are variable in their program coverage of environmental sample types. One of the primary objectives in establishing a nationally consistent accreditation program is to improve data quality while making better use of state and laboratory resources through mutual recognition. Unfortunately, many laboratories holding NELAP accreditation are still forced to meet too many different sets of state and EPA program requirements, all of which are intended to achieve the same objectives for data quality. Therefore, we must conclude, there still is not a coordinated effort for an effective and cost efficient nation-wide program to ensure the quality of all environmental data.

COMMON GOALS

EPA, all states and the NELAC community share a common goal for ensuring laboratory competence and data quality which can be accomplished by a single national laboratory accreditation program. Resources could be better utilized if a more efficient partnership of the federal, state and regulated communities was formed. NELAC is in the process of establishing a self-sufficient and independent organization which will allow for this partnership to continue and achieve the CNAEL goals to: "simplify the current system of multiple laboratory accreditation programs by promoting reciprocity and leveling the differences between the various state programs and promoting uniform standards for all aspects of laboratory performance."

It is clear that the state accrediting authorities and regulated community alone can not move the NELAC program forward as it was envisioned by the recommendations in the CNAEL report. ***To be successful, NELAC needs EPA program offices to participate as truly engaged partners with a commitment to harmonize all Agency and NELAC requirements and programs designed to ensure the quality of all compliance data submitted to and used by the EPA.***

A PLACE TO START

The purpose of this document is to provide a framework for discussions with all relevant EPA program offices as to how the EPA and NELAC can work together to ensure NELAP meets the data quality and laboratory certification requirements of each EPA office. We recommend starting first with the EPA Office of Water (OW) for the following reasons:

1. NELAP accreditation achieves the same objective as the EPA drinking water certification program. This was confirmed by the July 2002 memorandum from Cynthia Dougherty, Director, Office of Ground Water and Drinking Water (OGWDW), who stated NELAP accreditation satisfies the statutory requirements of the Safe Drinking Water Act;
2. The fifth edition of the OW Drinking Water Certification Manual provides excellent requirements to ensure the quality of drinking water data. While taking a slightly different approach, the NELAC Standard achieves the same end result. This should not be surprising as many of the same EPA, state and private sector staff have contributed to the development of both standards;
3. The NELAC standard is also designed to ensure the quality of wastewater data for which OW is also responsible;
4. Many laboratories perform both drinking water and wastewater analyses, which require virtually the same quality systems, facilities, staffing and technologies;
5. The NELAC community is committed to respond to the EPA OW needs for laboratory certification and data quality; and
6. When budgets are under pressure, it is hard to justify the duplicative resources necessary to maintain the separate but equivalent EPA drinking water certification and the NELAP accreditation programs.

BENEFITS TO EPA PROGRAM OFFICES

In developing a new self-sufficient and independent NELAC organization, the stakeholders (i.e., EPA, other federal and state agencies and private sector participants) can provide the following programs and services:

- Provision of an OMB A-119 compliant NELAC Standard with increased flexibility to meet the needs of EPA programs requiring adherence to promulgated methods and associated quality assurance, and those allowing a performance–based analytical approach;

- Management of a rigorous, consistent national environmental laboratory accreditation program (NELAP) that will harmonize all current EPA and state accreditation programs;
- Recognition and coordination of state and federal accreditation programs;
- Management of all aspects of PT programs;
- Training of laboratory assessors, management personnel and technical staff;
- A mentoring program for implementation of the new NELAC Standard into state and federal accreditation programs;
- A mentoring program for implementation of the new NELAC Standard by commercial, industrial, municipal, state and EPA laboratories;
- A forum to share information and better train laboratory assessors to promote nationally consistent evaluations;
- A national database for the listing of accredited laboratories, and a PT database for assessing the quality and compliance of PT studies.

CONCLUSION

Quality data is critical to ensuring the decisions we make, and the information on environmental quality we provide the public, are reliable. While many of the EPA and state environmental programs operate under separate statutory and regulatory authorities, they all have a common need for data of known and documented quality. Considering the size and complexity of the community of environmental monitoring organizations and the regulations they must help comply with, the only practical means of effectively assessing and ensuring competence is through a nationally consistent laboratory accreditation program. While no one program alone can ensure the quality of all environmental monitoring data, accreditation provides the foundation upon which to build all other data quality assurance programs.

The Special Committee and NELAC Board of Directors suggest that NELAP offers an optimal framework to manage such an accreditation program that can meet EPA, state and other federal agency needs. This can best be accomplished through the continued development and support of the NELAC Standard by an OMB A-119 compliant consensus process with open and equal participation by EPA program offices, other federal, state and private sector stakeholders. ***As EPA and the states are mandated to ensure the quality of data that are used to assess and ensure regulatory compliance, it is essential that the national laboratory accreditation program be directed***

solely by state and federal personnel in an open process with appropriate consultation and input from all affected stakeholders.

Continued EPA leadership is critical to achieve our common goals. In a time of shrinking budgets, partnerships between governments and the regulated community have never been more important. ***The NELAC Board wishes to explore with EPA its vision as to how the EPA can best participate to help ensure the success of the national environmental laboratory accreditation effort.***

Since the EPA OW has statutory authority to implement and enforce laboratory certification under the federal Safe Drinking Water Act, and many states in turn accredit their drinking water laboratories through primacy, we consider it logical to first develop a cooperative accreditation program between OW and NELAP. This cooperative program can be established in a way that complements and enhances EPA's regulatory and oversight authority. We believe these are compelling reasons to come together and explore the use of NELAC as the starting point in harmonizing the EPA's data quality assurance and laboratory accreditation requirements.

REFERENCES

(1) "Data Quality Act," issued by the Office of Management and Budget (OMB) under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658).
(2) "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," USEPA, EPA/260R-02-008, October, 2002.
(3) "Policy and Program Requirements for the Mandatory Agency-Wide Quality System," EPA Order 5360.1 A2, May 5, 2000.
(4) "A Report to Congress: Availability, Adequacy, and Comparability of Testing Procedures for the Analysis of pollutants Established Under section 304(h) of the Federal Water Pollution Control Act," USEPA, EPA/600/9-87/030, September 1988.
(5) "Final Report of the Committee on National Accreditation of Environmental Laboratories (CNAEL)," September, 1992.

SPECIAL COMMITTEE MEMBERS

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